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EXAMINER

DUNSTON, JENNIFER ANN

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1636

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

This action is in response to the amendment, filed 6/23/2008, in which claims 1, 2, 14, 15, 17-20, 22-26, 28, 30 and 32 were canceled, and claims 4-7, 10, 12 and 13 were amended. Currently, claims 3-13, 16, 21, 27, 29, 31 and 33 are pending.

Applicant's arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and objections not reiterated in this action have been withdrawn. **This action is FINAL.**

Response to Arguments - Drawings

The drawings were received on 6/23/2008. These drawings are accepted.

Response to Arguments - Claim Objections

The objection of claims 5 and 6, as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, has been withdrawn in view of Applicant's amendment to the claims in the reply filed 6/23/2008.

Response to Arguments – Double Patenting

Applicant's arguments, see page 8, filed 6/23/2008, with respect to the provisional rejection of claims 1-4, 10-15 and 26-33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/511,496 have been fully considered and are persuasive. Application No. 10/511,496 is now abandoned. The previous rejection of claims 1-4, 10-15 and 26-33 has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3-13, 16, 21, 27, 29, 31 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Ashby (US Patent No. 6,613,520 B2; see the entire reference). This rejection was made in the Office action mailed 3/20/2008 and has been rewritten to address the amendments to the claims in the reply filed 6/23/2008.

Regarding claim 3, Ashby teaches a method for determining an environmental condition by measuring the marker diversity profile of a microbial population of an environmental sample, where the marker is characteristic of a particular genome in the population of interest (e.g., column 3, line 60 to column 4, line 49; column 8, lines 41-56; column 9, lines 1-29; column 10, line 5 to column 13, line 67). To analyze the marker data, Ashby teaches the steps of making a database containing reference data files which are collections of diversity profiles that provide an accurate representation of members present in a particular population, correlating the measured diversity profiles with the profiles in the database for diagnostic purposes, thereby determining a particular environmental condition such as the presence of mineral deposits, petroleum reserves,

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or microbial contamination of human and animal foodstocks (e.g., column 3, line 60 to column 4, line 49; column 8, lines 41-56; column 14, line 1 to column 17, line 15; Figures 9 and 10).

Regarding claim 4, Ashby teaches the method where the microbial population comprises bacteria or fungi (e.g., column 9, lines 1-5).

Regarding claim 5, Ashby teaches the method where the microbial population is soil flora (e.g., column 10, lines 5-10).

Regarding claim 6, Ashby teaches the method where the microbial population is a naturally occurring population in a specific environmental sample used in the process (e.g., column 8, lines 33-56; column 10, lines 5-55).

Regarding claims 7 and 8, Ashby teaches the method where the measuring comprises the use of taxon-specific nucleic acid markers (e.g., paragraph bridging columns 3-4; column 9, lines 6-16).

Regarding claim 9, Ashby teaches the method where the marker diversity is measured by hybridizing microbial rDNA to immobilized oligonucleotides in DNA microarrays (e.g., Example 7).

Regarding claims 10-13, Ashby teaches the claimed method step of measuring a composition of a microbial population which has been exposed to an environmental condition. To analyze the marker data, Ashby teaches the steps of making a database containing reference data files which are collections of diversity profiles that provide an accurate representation of members present in a particular population, correlating the measured diversity profiles with the profiles in the database for diagnostic purposes, thereby determining a particular environmental condition such as the presence of mineral deposits, petroleum reserves, or microbial

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contamination of human and animal foodstocks (e.g., column 3, line 60 to column 4, line 49; column 8, lines 41-56; column 14, line 1 to column 17, line 15; Figures 9 and 10). Thus, the teachings of Ashby meet each of the limitations of the rejected claims.

Regarding claim 16, Ashby teaches the method where the measuring comprises the use of taxon-specific nucleic acid markers (e.g., paragraph bridging columns 3-4; column 9, lines 6-16).

Regarding claim 21, Ashby teaches the method where the marker diversity is measured by hybridizing microbial rDNA to immobilized oligonucleotides in DNA microarrays (e.g., Example 7).

Regarding claims 27, 29, 31 and 33, Ashby teaches the claimed method steps of (i) measuring a composition of a microbial population which has been exposed to an environmental condition, (ii) correlating said composition to a previously compiled reference data file of a plurality of compositions obtained through exposure of said microbial population to a plurality of environmental conditions, and (iii) determining said environmental condition on the basis of the outcome of said correlation. Specifically, Ashby teaches a method for determining an environmental condition by measuring the marker diversity profile of a microbial population of an environmental sample, where the marker is characteristic of a particular genome in the population of interest (e.g., column 3, line 60 to column 4, line 49; column 8, lines 41-56; column 9, lines 1-29; column 10, line 5 to column 13, line 67). To analyze the marker data, Ashby teaches the steps of making a database containing reference data files which are collections of diversity profiles that provide an accurate representation of members present in a particular population, correlating the measured diversity profiles with the profiles in the database for diagnostic purposes, thereby determining a particular environmental condition such as the

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presence of mineral deposits, petroleum reserves, or microbial contamination of human and animal foodstocks (e.g., column 3, line 60 to column 4, line 49; column 8, lines 41-56; column 14, line 1 to column 17, line 15; Figures 9 and 10). Thus, the teachings of Ashby meet each of the limitations of the rejected claims.

Response to Arguments - 35 USC § 102

The rejection of claims 1, 2, 4, 7, 8, 10-14, 16, 17, 19, 26, 28, 30 and 32 under 35 U.S.C. 102(b) as being anticipated by Welling et al has been withdrawn in view of Applicant's amendment to the claims in the reply filed 6/23/2008.

The rejection of claims 1, 2, 4, 7-14, 16, 17, 19, 21, 22, 24, 26, 28, 30 and 32 under 35 U.S.C. 102(b) as being anticipated by Rudi et al has been withdrawn in view of Applicant's amendment to the claims in the reply filed 6/23/2008.

The rejection of claims 1, 4, 7-13, 16 and 21 under 35 U.S.C. 102(e) as being anticipated by Mirzabekov et al has been withdrawn in view of Applicant's amendment to the claims in the reply filed 6/23/2008.

The rejection of claims 1, 2, 14, 15, 17-20, 22-26, 28, 30, 32 under 35 U.S.C. 102(e) as being anticipated by Ashby is moot in view of Applicant's cancellation of the claims in the reply filed 6/23/2008.

With respect to the rejection of claims 3-13, 16, 21, 27, 29, 31 and 33 under 35 U.S.C. 102(e) as being anticipated by Ashby, Applicant's arguments filed 6/23/2008 have been fully considered but they are not persuasive.

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The response asserts that Ashby does not analyze a fixed, controlled microbial population and measure the changes in that population caused by environmental circumstances as required by claim 3. This is not found persuasive, because claim 3 is drawn to the measurement of any composition of a microbial population. The claims do not require a population that is fixed or controlled. The specification envisions using microbial populations already present in the environment (page 3, lines 26-30). Even if the claims included the words "fixed" or "controlled", the specification does not explicitly define these terms. A microbial population may be fixed or controlled by environmental conditions. As stated on page 3, lines 8-11 of the specification, "A microbial population as a whole may be used as a measuring instrument for determining an environmental condition and/or change therein because the composition of this population reflects the prevailing environmental condition." Similarly, Ashby teaches that microbes have defined nutrient requirements and thus have a restricted distribution in the environment, allowing the microbes to function as environmental biosensors (e.g., column 8). In other words, the population of microbes reflects the environmental condition.

The response asserts that Ashby is distinguished from the claimed invention, because Ashby merely characterizes an existing microbial population found in an unknown environmental condition. The response asserts that the claims require the same microbial population to be used in compiling the reference data as in the measuring step. The response asserts that the claimed method tests the same population of microbes in different environments and also can look at changes in microbial species that may not be found in the environment under investigation, which is neither taught nor suggested by Ashby. This is not found persuasive. Ashby teaches measuring population of soil microbes, for example, under different

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conditions. The same population (i.e., population of soil microbes) is tested in various known conditions in order to compile a database. Then, the population of soil microbes is tested in the unknown conditions, correlated to the previously compiled reference database, thereby determining the environmental condition on the basis of the outcome of the correlation (e.g., e.g., column 3, line 60 to column 4, line 49; column 8, lines 41-56; column 9, lines 1-29; column 10, line 5 to column 13, line 67; column 14, line 1 to column 17, line 15). Although the claims may encompass the measurement of changes in microbial species not found in the environment under investigation, the claims are not limited to this embodiment. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the use of microbes not found in the environment under investigation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 6 requires the microbial population to be introduced into or occurring naturally in a specific process. Ashby teaches microbial populations occurring naturally. Thus, the teachings of Ashby meet the limitations of the rejected claims.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Conclusion

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached at 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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